

## CLAIMS

1. A pharmaceutical composition in a form of an anhydrous self-nanoemulsifying oily formulation comprising:
- 5           - one or more therapeutic agent(s) which have low solubility in water or are water-insoluble,
  - vitamin E,
  - one co-solvent selected from propylene glycol and ethanol and mixture thereof
  - 10          - one surfactant selected from tyloxapol and from mixture of tyloxapol and TPGS, and optionally,
  - a bioenhancer.
2. A pharmaceutical composition according to claim 1 further comprising an
- 15   acidic pH adjuster.
3. A pharmaceutical composition according to anyone of claims 1 to 2, wherein vitamin E is from 2 to 6% (w/w) of the final composition.
- 20   4. A pharmaceutical composition according to anyone of claims 1 to 3, wherein the one or more therapeutic agent(s) is selected from the group comprising anti-fungal drugs, anti-viral drugs, antibiotic drugs, anti-inflammatory drugs, anti-cancer drugs, analgesics, antidepressants, antipsychotics, hormones, antacids, coronary vasodilators, cerebral vasodilators, psychotropics, antineoplastics,
- 25   stimulants, anti-histamines, vasodilators, anti-arrhythmics, anti-hypertensive drugs, vasoconstrictors, anti-migraine drugs, anti-coagulants and anti-thrombotic drugs, anti-pyretics, hypnotics, sedatives, anticonvulsants, anti-epileptics, neuromuscular drugs, drugs acting on Central Nervous System, hyper- and hypoglycemic agents, diuretics, anti-obesity drugs, anabolic drugs, anti-uricemic drugs,
- 30   immunosuppressant drugs and combinations thereof.

5. A pharmaceutical composition according to anyone of claims 1 to 4, wherein the one or more therapeutic agent(s) is selected from the group comprising anti-cancer drugs, antineoplastic drugs and combinations thereof.
- 5 6. A pharmaceutical composition according to anyone of claims 1 to 5, wherein the anti-cancer drug is a taxoid, preferably selected from paclitaxel, docetaxel, their derivatives, analogs and prodrugs.
7. A pharmaceutical composition according to anyone of claims 1 to 6, wherein  
10 the taxoid is paclitaxel in a relative proportion between 0.5 and 4% (w/w) of the final composition, preferably between 1.5 and 3% (w/w).
8. A pharmaceutical composition according to anyone of claims 1 to 7, wherein the relative proportions of vitamin E, TPGS and tyloxapol are respectively 2-6, 0-  
15 60 and 5-70 (w/w) of the final composition, preferably respectively 2-6, 5-60 and 5-70 (w/w) of the final composition, more preferably respectively 3-5, 20-40 and 20-40%.
9. A pharmaceutical composition according to anyone of claim 1 to 8 wherein the  
20 relative proportion of propylene glycol is in the range of 0-50% (w/w) of the final composition, preferably equal to 20% (w/w) and the relative proportion of ethanol is in the range of 5-50% (w/w) of the final composition, preferably equal to 30% (w/w).
- 25 10. A pharmaceutical composition according to anyone of claims 1 to 9, wherein the enhancer is selected from the group comprising cytochrome P450 2C8 inhibitors, cytochrome P450 3A4 inhibitors, multidrug resistance inhibitors, Pgp inhibitors or non specific inhibitors.
- 30 11. A pharmaceutical composition according to claim 10, wherein the enhancer is cyclosporine A, its analogs and derivatives.

12. A pharmaceutical composition according to anyone of claims 2 to 11, wherein the acidic pH adjuster is anhydrous citric acid.

13. A pharmaceutical dosage form comprising an anhydrous self-nanoemulsifying oily formulation composition according to anyone of claims 1 to 12 associated to suitable pharmaceutical excipients.

14. A pharmaceutical dosage form according to claim 13, which is suitable for the oral route.

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15. A pharmaceutical dosage form according to claim 14 wherein the composition is encapsulated in a soft or hard gelatin capsule or is a liquid oily preparation.

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16. A pharmaceutical dosage form according to claim 13, which is suitable for the intravenous route.

17. Use of an anhydrous self-nanoemulsifying oily formulation according to anyone of claims 1 to 12 for the manufacture of a medicament useful in the treatment of taxoid-responsive diseases.

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18. Use according to claim 17 for administration to patients receiving simultaneously with, concomitantly or prior to, bioavailability enhancing agent and/or another antitumor agent.

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19. Use of an anhydrous self-nanoemulsifying oily formulation according to anyone of claims 1 to 12 for the manufacture of a medicament wherein the dose of the therapeutic agent administered is linearly proportional to the blood plasma level of the therapeutic agent desired.

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20. Use of tyloxapol and of mixture of tyloxapol and TPGS, for preparing pharmaceutical composition in the form of anhydrous self-nanoemulsifying oily

formulation suitable for preparing a medicament wherein the dose of the therapeutic agent administered is linearly proportional to the blood plasma level of the therapeutic agent desired.

5. 21. Method of treatment of taxoid-responsive diseases wherein an effective amount of a composition according to claim 1 is administered to a patient in the need thereof.